



DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

SEP 5 2002

The Honorable Henry A. Waxman
Ranking Minority Member
Committee on Government Reform
U.S. House of Representatives
B350A Rayburn House Office Building
Washington, D.C. 20515

Dear Congressman Waxman:

Thank you for your letter of July 26, 2002, requesting information on the Department of Agriculture's (USDA) actions regarding the recent *E. coli* O157:H7 outbreak associated with meat produced at ConAgra Beef Company's Greeley, Colorado plant.

I share your concerns about this outbreak and agree that protecting our food supply for consumers is paramount. I also appreciate the opportunity to clarify the circumstances surrounding the outbreak and the subsequent massive recall of meat products. As I have stated repeatedly, my highest priority is protecting public health through a rigorous system of meat and poultry inspection based on science. Tragically, a number of consumers became ill from the consumption of meat produced by the ConAgra Beef Greeley plant. This is deeply troubling to me both personally and professionally.

However, any impartial review of the Food Safety and Inspection Services' (FSIS) response in this case would demonstrate that they acted expeditiously, deliberately and decisively. We were motivated by our dedication to protect public health and ensure a safe and wholesome food supply. FSIS' response time, between the first cases of *E. coli* O157:H7 and the massive recall, was significantly faster than in previous incidents of this size and complexity.

As soon as FSIS learned about the first illnesses linked to ConAgra ground beef in mid-July from the Centers for Disease Control and Prevention (CDC), FSIS deployed an additional team of top scientific and technical experts to join the FSIS in-depth verification team, which was already in the plant conducting an investigation of the likely cause of the contamination. The investigators were led by the Agency's Deputy Administrator for Field Operations, William Smith, and included FSIS epidemiologists, microbiologists and food technologists, who were quickly on-site to begin this review. The team examined a wide range of operations, including production practices, plant records and completed laboratory analyses. What they found in a matter of a few days led us to the ConAgra Beef recall.

It should be noted here that the illnesses associated with the largest beef recall in history, involving Hudson Foods, actually occurred beginning June 1, 1997, but were not epidemiologically associated with the product until mid-August of that year-which led to the Hudson Foods recall. In the ConAgra Beef outbreak, by contrast, a link between June/July illnesses and the product ultimately recalled was confirmed by the CDC on July 15, 2002, after the initial recall was requested by FSIS.

The ConAgra Beef recall was only one of a number of actions that we took to protect public health. Right from the start, we changed a long-standing FSIS policy and ordered that all suppliers to a processing plant be notified-both verbally and in writing-whenver there is a positive *E.coli* O157:H7 finding. Furthermore, we recognized that, while it is important to confirm laboratory results indicating *E.coli* O157:H7 contamination, there are actions FSIS can take while awaiting laboratory results. When the laboratory has reported a presumptive positive (80-90 percent confidence of a positive, typically 2 days before confirmation), FSIS will immediately begin to gather records on the suppliers. FSIS will also print the coded follow-up sample collection forms and prepare sample collection supplies and boxes for shipping. In this way, FSIS will be ready to act immediately with notification and follow-up sampling whenever FSIS laboratories confirm a positive result.

This is a significant development on a number of levels. Most prominently, such action had never been taken before. Moreover, this rapid notification allows suppliers to begin their own investigation into a potential problem, which can include increased laboratory sampling, holding production lots or conducting an audit of a firm's Pathogen Reduction/Hazard Analysis and Critical Control Point (HACCP) plan for errors and potential weakness. The policy change also increases the amount of private-sector, scientific resources that can be devoted to a potential contamination situation beyond what is available at FSIS. This decision, while it cannot expedite scientific confirmation, may allow us-and all participants in the meat distribution cycle-to respond more quickly to indicators of a problem.

Another important step in our response was our decision to include beef trimmings, or trim, in the recall. This measure, also a first, was completed in the interest of public health after thoughtful deliberations between our on-site team and Washington-based scientific experts. We concluded that the heightened prospect of *E. coli* O157:H7 in trimmings warranted such a decisive action. I have commended those who worked on this issue for thinking strategically about how to limit the spread of potentially contaminated product. An on-going examination of ConAgra's HACCP systems is taking place in an effort to ensure that measures are taken at each step in their production cycle to reduce the risk of pathogens and to ensure that the plant is producing safe product.

The Honorable Henry E. Waxman
Page 3

Our work in this case is far from over. The *E. coli* O157:H7 verification sampling is ongoing at the ConAgra Beef Greeley plant and will continue at a heightened rate until we are convinced that this problem is under control. FSIS also issued a "Notice of Intended Enforcement" to ConAgra Beef because of deficiencies we discovered in their HACCP plans during our in-depth review, and ConAgra is in the process of addressing those shortcomings.

This case also requires FSIS to re-evaluate its policies about overall recall management practices and FSIS is in the process of doing just that. Reviewing exactly how FSIS responds to these types of events is critical to improving their performance in the future. If FSIS determines that there are areas that can be enhanced, then we will act responsibly and quickly to make those changes as we did in the ConAgra recall. There will be no end to our vigilance and determination when it comes to protecting public health.

I have enclosed a detailed timeline that provides an extensive account of FSIS' actions in relation to the recall. The timeline answers the specific questions raised in your recent letter and provides additional information that may be helpful. We would be happy to meet with you in the future to provide any additional information or details related to this case.

Thank you again for your interest in this issue. I am sending an identical response to each of your colleagues who has signed the letter.

Sincerely,

A handwritten signature in black ink, appearing to read 'E. Murano', with a long horizontal flourish extending to the right.

Dr. Elsa A. Murano
Under Secretary
Food Safety

Enclosures

Chronology of FSIS Sampling and Actions in ConAgra (est. 969) and Galligan's Wholesale Meat Co. (est. 6475)

Date of Sample Collection or FSIS Action	Facility	Sample Ship Date	Sample Test Result	Description of FSIS Actions
01/22/2001	Galligan's (6475)	01/22/2001	Reported Negative on 1/25.	
03/01/2001	ConAgra (969)	03/01/2001	Reported Negative on 3/4.	
03/20/2001	Galligan's (6475)	03/20/2001	Reported Negative on 3/24.	
06/19/2001	Galligan's (6475)	06/19/2001	Reported Negative on 6/21.	
08/14/2001	Galligan's (6475)	08/14/2001	Reported Negative on 8/16.	
08/30/2001	ConAgra (969)	-	-	ConAgra produced and shipped approximately 509 cases (41,020 pounds) of 81/19 coarse ground beef to ConAgra Beef-Swift Support Center.
10/15/2001	Galligan's (6475)	10/15/2001	Reported Negative on 10/17.	
12/20/2001	Galligan's (6475)	12/20/2001	Reported Negative on 12/22.	
03/08/2002	Galligan's (6475)	03/08/2002	Reported Negative on 3/10.	
03/19/2002	ConAgra (969)	03/19/2002	Reported Negative on 3/23.	
05/09/2002	Galligan's (6475)	05/09/2002	Reported Positive on 5/14.	
05/14/2002	Galligan's (6475)	-	5/9 Sample Reported Positive.	Confirmed positive for <i>E. coli</i> 0157:H7; no recall was necessary because the company held all the product. FSIS scheduled 15 follow-up samples for testing at Galligan's.
05/20/2002	Galligan's (6475)	-	-	FSIS issued an NR for positive result reported on 5/14 and directed the establishment to reassess their HACCP plan.
05/28/2002	Galligan's (6475)	05/28/2002	Reported Negative on 5/30.	
05/31/2002	ConAgra (969)	-	-	Date of production of original ConAgra ground beef implicated in 6/30 recall.
06/04/2002	Galligan's (6475)	06/04/2002	Reported Negative on 6/8.	
06/05/2002	Galligan's (6475)	06/05/2002	Reported Negative on 6/9.	
06/11/2002	Galligan's (6475)	06/11/2002	Reported Negative on 6/15.	
06/12/2002	Galligan's (6475)	06/12/2002	Reported Positive on 6/17.	5 th sample from the 15 scheduled follow-ups.
06/13/2002	Galligan's (6475)	06/13/2002	Reported Negative on 6/15.	
06/14/2002	Galligan's (6475)	06/14/2002	Reported Positive on 6/19.	7 th sample from the 15 scheduled follow-ups. Allegedly only ConAgra product had been supplied (produced by ConAgra on May 31); however, other

Date of Sample Collection or FSIS Action	Facility	Sample Ship Date	Sample Test Result	Description of FSIS Actions
				sources may have been incorporated into the ground beef. Company held product on site.
06/17/2002	Galligan's (6475)	-	6/12 Sample Reported Positive.	Allegedly only ConAgra product produced on May 31 had been supplied; however, other sources may have been incorporated into the ground beef. This establishment had a history of adding its own trimmings and had no documentation to prove it had not done so in this case. Company held product on site.
06/18/2002	ConAgra (969)	-	-	Freeze or sell by date of ConAgra product implicated in 6/30 recall (produced 5/31/2002).
06/18/2002	Galligan's (6475)	-	-	FSIS issued NR for positive result reported on 6/17 and directed the establishment to reassess its HACCP plan.
06/19/2002	-	-	6/14 Sample Reported Positive.	NR issued for positive result from 6/14 sample. Establishment continued to allege that only ConAgra product had been supplied. An FSIS compliance team was dispatched to initiate an investigation. Safeway launches a buy one, get one free sale on ground beef for 6 days, until June 24.
06/20/2002	Galligan's (6475)	-	-	Of 160 pounds of product located at Galligan's, FSIS took detained two 10-pound chubs. 140 pounds were returned to ConAgra and held by the company.
06/21/2002	Galligan's (6475)	06/21/2002	Reported Negative on 6/23.	
06/24/2002	Galligan's (6475)	Samples shipped 06/24/2002.	Reported Positive on 6/29.	Samples collected and taken from the unopened product detained on 6/20 (two 10-pound chubs that Galligan's purchased from ConAgra with a 5/31 production date), in order to traceback source of contamination. FSIS scheduled 15 follow-up samples.
	ConAgra (969)	Samples shipped 06/24/2002.	Reported Positive on 6/29.	
06/24/2002	Galligan's (6475)	06/24/2002	Reported Negative on 6/26.	
06/25/2002	Galligan's (6475)	06/25/2002	Reported Negative on 6/27.	
06/26/2002	Galligan's (6475)	06/26/2002	Reported Negative on 6/28.	
06/27/2002	Galligan's (6475)	06/27/2002	Reported Negative on 6/29.	
06/27/2002	ConAgra (969)	-	Presumptive Positive from	ConAgra notified via e-mail of presumptive

Date of Sample Collection or FSIS Action	Facility	Sample Ship Date	Sample Test Result	Description of FSIS Actions
			Galligan's 6/20 Samples.	positive at Galligan's. This is done with the expectation that they will begin collecting distribution records. This is important because nine out of ten presumptive positives later report positive.
06/29/2002	ConAgra (969) from Galligan's (6475).	-	6/20 Sample Reported Positive.	Sample collected on 6/24 (detained on 6/20) tested positive for <i>E.coli</i> and FSIS initiates 15 follow-up samples. FSIS requested a voluntary recall.
06/30/2002	ConAgra (969)	-	-	Nationwide recall release issued by FSIS for approximately 354,000 pounds of fresh and frozen ground beef products produced on May 31. States affected include: AL, AZ, CA, CO, ID, IL, IA, KS, MD, MI, MN, MO, NE, NJ, NM, NY, TN, TX, VA, and WY.
07/01/2002	-	-	-	FSIS compliance officer (CO) and supervisory CO met with ConAgra.
				Safeway Stores in Colorado issued a recall of the hamburger meat.
07/02/2002	Galligan's (6475)	07/01/2002	Reported Negative on 7/3.	
	-	-	-	The 6/30 ConAgra recall triggered the dispatch of FSIS COs to conduct recall effectiveness checks. FSIS dispatched a consumer safety officer (CSO) to work with in-plant inspection personnel to review the company's reassessment of its HACCP plan.
				Safeway announced it sold some of the recalled hamburger meat.
	Galligan's (6475)	07/02/2002	Reported Negative on 7/4.	
07/05/2002	Galligan's (6475)	07/05/2002	Reported Negative on 7/7.	
07/08/2002	Galligan's (6475)	07/08/2002	Reported Negative on 7/10.	
07/10/2002	ConAgra (969)	-	-	Colorado State health officials reported an outbreak of 12 cases of <i>E. coli</i> 0157:H7 in 9 counties, inform public to return product from Safeway stores sold from June 7 to June 18. FSIS determined need for a full food safety investigation and a review team is

Date of Sample Collection or FSIS Action	Facility	Sample Ship Date	Sample Test Result	Description of FSIS Actions
07/11/2002	ConAgra (969)	07/12/2002	Discarded on 7/13.	dispatched to ConAgra plant. FSIS discarded sample due to inconsistency with chain of custody requirements.
07/12/2002	-	-	-	Colorado State health officials announced there were an additional 5 cases associated with the current illness outbreak, bringing the total to 17.
07/12/2002	ConAgra (969)	07/12/2002	Discard on 7/13.	FSIS discarded sample due to inconsistency with chain of custody requirements.
7/13/2002	ConAgra (969)	-	7/11 and 7/12 Samples Discarded.	FSIS discarded sample due to inconsistency with chain of custody requirements.
07/13/2002	ConAgra (969)	07/15/2002	Reported Negative on 7/17.	
07/15/2002	ConAgra (969)	-	-	CDC informed FSIS that PFGE pattern of patients' isolates in Colorado matches pattern of ConAgra chub isolate. Food Safety Review Team, led by FSIS Deputy Administrator for Field Operations Bill Smith, arrives at ConAgra. 2 CSOs, 1 EPI officer, 2 microbiologists, Inspection Coordinator, and Deputy District Manager initiated the review at ConAgra, in Greeley, CO.
				FSIS released statement on change to recall policy (FSIS will now inform suppliers to a further processing facility, both verbally and in writing, when a positive <i>E. coli</i> 0157:H7 sample is discovered in ground beef supplied to that facility).
07/15/2002	Galligan's (6475)	07/15/2002	Reported Negative on 7/19.	
	ConAgra (969)	07/16/2002	Reported Negative on 7/18.	
	ConAgra (969)	07/17/2002	Reported Negative on 7/19.	
07/17/2002	ConAgra (969)	-	-	FSIS Food Safety Review Team briefed Recall Committee of findings at ConAgra.
	Galligan's (6475)	07/17/2002	Reported Negative on 7/19.	
	ConAgra (969)	07/17/2002	Reported Negative on 7/19.	

Date of Sample Collection or FSIS Action	Facility	Sample Ship Date	Sample Test Result	Description of FSIS Actions
07/18/2002	ConAgra (969)	-	-	Recall Committee recommended ConAgra expand recall beyond the 354,200 pounds (May 31 production) to include product produced between April 12 and July 11 (approximately 19 million pounds). Accepted by ConAgra. Notice of Intended Enforcement action submitted to ConAgra (72 hours to respond).
07/19/2002	ConAgra (969)	07/18/2002	Reported Negative on 7/20.	
	ConAgra (969)	-	-	Recall of 26 production days worth of product by ConAgra announced by FSIS (approximately 19 million pounds).
07/20/2002	ConAgra (969)	07/22/2002	Reported Negative on 7/24.	
07/22/2002	ConAgra (969)	07/22/2002	Reported Negative on 7/26.	
	-	-	-	Conference call with CDC. CDC reported 21 confirmed cases of <i>E. coli</i> 0157:H7 that share the Colorado/ConAgra PFGE pattern. 17 cases were from CO, with one each from the four states of MI, SD, WA, and WY.
	ConAgra (969)	07/22/2002	Reported Negative on 7/24.	
07/23/2002	Galligan's (6475)	07/23/2002	Reported Negative on 7/25.	
	ConAgra (969)	07/24/2002	Reported Negative on 7/26.	
07/24/2002	ConAgra (969)	07/25/2002	Reported Negative on 7/27.	
07/25/2002	Galligan's (6475)	07/25/2002	Reported Negative on 7/27.	
	ConAgra (969)	07/26/2002	Reported Negative on 7/28.	
07/26/2002	Galligan's (6475)	07/26/2002	Reported Negative on 7/28.	
	ConAgra (969)	07/29/2002	Reported Negative on 7/31.	
07/27/2002	ConAgra (969)	07/29/2002	Reported Negative on 7/31.	
07/29/2002	ConAgra (969)	07/30/2002	Reported Negative on 8/1.	
07/30/2002	ConAgra (969)	07/30/2002	Reported Negative on 8/1.	
08/02/2002	ConAgra (969)	08/02/2002	Discarded on 8/7.	FSIS discarded sample due to sample collection irregularities.
08/09/2002	ConAgra	-	-	CDC reported 34 confirmed cases in 10 States of <i>E. coli</i> 0157:H7 that share the Colorado/ConAgra PFGE pattern. Additional cases are pending confirmation for sharing the same PFGE pattern.